

LEAVING MEDICARE BENEFICIARIES IN LIMBO



PARTNERSHIP TO FIGHT
CHRONIC DISEASE



Medicare Uses Coverage with Evidence Development to Limit Access: By the Numbers

27

NCDS WITH CED
ISSUED SINCE THE
PROGRAM'S START
IN 2005

11.5

YEARS: AVERAGE TIME
FROM CED START UNTIL
MEDICARE RETIRED
THE CED*

22

CURRENTLY
ACTIVE NCDS
WITH CED

13.5

YEARS OF LONGEST
ONGOING CED WITH
CLINICAL TRIALS

33

LARGEST NUMBER
OF CLINICAL
TRIALS REPORTED
FOR AN ACTIVE CED

13

YEARS OF LONGEST
ONGOING CED WITH
REGISTRIES

4

NCDS WITH
CED EVIDENCE
COLLECTION
RETIRED*

1

NCD WITH CED FOR FDA-
APPROVED THERAPIES
DENYING COVERAGE FOR
THEIR MEDICALLY
APPROPRIATE, CLINICALLY
APPROVED USE
(ALZHEIMER'S DISEASE).

* ONCE A CED REQUIREMENT IS DEEMED COMPLETED BY MEDICARE, MEDICARE WILL COVER THE PRODUCT WITHOUT REQUIRING PARTICIPATION IN A CLINICAL STUDY.

SOURCES: EP ZEITLER & LG GILSTRAP. COVERAGE WITH EVIDENCE DEVELOPMENT: WHERE ARE WE NOW? AM I MANAG C. 2022;28(8): 382-89; CMS NCD DATABASE.

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Coverage with Evidence Development (CED) Limits Patient Access:

Medicare may deny coverage of FDA-approved treatments or services through a National Coverage Determination requiring CED, which limits Medicare coverage only to beneficiaries participating in an approved clinical research study.

No one has coverage unless and until the clinical research study is open, is enrolling patients, and the patient meets the necessary eligibility requirements for the study and is enrolled.

CED Delays Coverage and Restricts Access:

CED's stated purpose is to collect additional data Medicare will use to re-assess coverage in the future. But the CED process has taken 11.5 years on average before retiring evidence collection – during that time beneficiaries have limited access and no clear time frame for when the coverage limitations will be revisited.

CEDs Adversely Impacts Underserved Populations and Exacerbates Health Disparities:

CED clinical study requirements favor large, urban medical centers and often leave out rural populations without access. These CED clinical trials and registries have historically had a poor record of enrolling diverse participants.



**MEDICARE BENEFICIARIES SHOULDN'T HAVE TO
WAIT TO ACCESS FDA-APPROVED TREATMENTS.
CED REQUIREMENTS ARE NOT THE ANSWER.**



Learn more at www.fightchronicdisease.org.